510(k) Summary of Safety and Effectiveness
Stryker Spine Xia® III Spinal System

AUG 27 2007

Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	**Ms. SIMONA VOIC** **REGULATORY AFFAIRS PROJETC MANAGER** **TELEPHONE: 201-760-8145** **FAX: 201-760-8345** **EMAIL:** simona.voic@stryker.com
Date Prepared	May 14, 2007
Trade Name	Stryker Spine Xia® III Spinal System
Proposed Class	Class III and II
Classification Name and Number	Pedicle Screw Spinal System 21 CFR 888.3070 Spinal Interlaminal Fixation Orthosis 21 CFR 888.3050
Product Code	NKB, MNH, MNI, and KWP
Predicate Devices	Stryker Spine Xia® Spinal Systems: 510(k) #K060361, K060979, and #K013823, Stryker Spine Radius™ Spinal System: 510(k) # K062270, DePuy's Moss Miami Spinal System: 510(k) #K950697.

Device Description	The Stryker Spine Xia® III Spinal System is comprised of monoaxial & polyaxial bone screws, blocker (as a locking mechanism), rods , hooks, and connectors. The implants are manufactured from Ti6Al4V alloy, and CPTi. The subject system also offers MoCoCr alloy (Vitallium) rods.
Intended Use	The Stryker Spine XIA® III Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the XIA®III Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e., fracture or dislocation); • Spinal stenosis; • Curvatures (i.e., scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion. The Ø5.5mm rods from the Stryker Spine Radius™ Spinal System and Ø6.0 mm Vitallium rods from XIA® Spinal System are intended to be used with the other components of Xia® III Spinal System.

Summary of the Technological Characteristics	Testing in compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was performed for the Xia® III Spinal System, and demonstrated substantial equivalent performance characteristics to the predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
% Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

AUG 2 7 2007

Re: K071373
Trade/Device Name: Xia® III Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Dated: August 1, 2007
Received: August 2, 2007

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071373

Device Name: Stryker Spine Xia® III Spinal System

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- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

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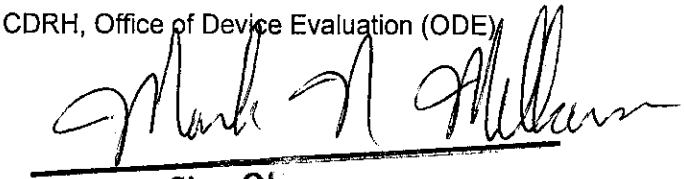
Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K071373